Notice of Allowability	Application No.	Applicant(s)	
	09/380,337	CHANDRASEKHARAPPA ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *amendments filed 12/18/2006, 8/29/2007, telephone Interview*.

2. ☐ The allowed claim(s) is/are *1, 3-4, 24, 26, 30, 32-33, 36-37, 43, 45, 47-51, now renumbered 1-17 respectively*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Susan Ungar
Primary Examiner
Art Unit: 1642

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. ∋ 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

2. The Amendment filed June 21, 2007 in response to the Office Action of December 18, 2006 and the Supplement Amendment filed August 29, 2007 in response to the Interview of August 22, 2007 are acknowledged and have been entered. Previously pending claims 3, 24, 26, 30, 32-33, 36, 43, 45, 47 were amended, claims 48-51 were added and claims 2, 5-23, 25, 27-29, 31, 34-35, 38-42, 44, 46 stand canceled. Claims 1, 3-4, 24, 26, 30, 32-33, 36-37, 43, 45, 47-51 are currently under prosecution.

3. The application has been amended as follows:

In the specification:

On page, line 1 after "This application claims priority to U.S. Provisional Patent Application Serial No. 60/040,269, filed March 5, 1997" the phrase --now abandoned-- was inserted.

In the claims:

The following claims have been amended as follows:

24. (Currently amended) A kit for detecting in a test sample the presence or absence of a mutation in a MEN1 gene having the sequence of SEQ ID NO:3, the kit comprising;

~~an oligonucleotide sequence that hybridizes to a target region in exon 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3;~~ an oligonucleotide competent to discriminate between the wildtype gene and a mutant form, wherein the oligonucleotide discriminates between the wildtype gene and mutant form in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3; and a reagent for detecting said discrimination ~~the formation of a duplex between the gene and the oligonucleotide sequence~~.

26. (currently amended) The kit of claim 24, further comprising amplification primer pairs for specifically amplifying exons 2 through 10 of MEN1, SEQ ID NO:3, either individually or in groups ~~specifically by hybridizing to a human MEN1 gene, SEQ ID NO:3~~.

30. (currently amended) An isolated cell transfected with a nucleic acid comprising the nucleic acid of claim 1.

32. (currently amended) The isolated cell of claim 30, wherein the transfected nucleic acid comprises SEQ ID NO:3.

43. (currently amended) A method for detecting the presence or absence of a mutation in a target region in exon 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3 in a nucleic acid sample, the method comprising:

~~a)~~ contacting the nucleic acid sample with an oligonucleotide ~~probe to the target region in exon 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3~~ corresponding to the wildtype SEQ ID NO:3, wherein the oligonucleotide discriminates between the wildtype gene and mutant form in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3; ~~and,~~

contacting a normal control sample comprising the wildtype exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3 with said oligonucleotide; and

~~b) detecting~~ comparing the formation of a duplex in the nucleic acid sample between said oligonucleotide and said target region in exon 2, 3, 4, 5, 6, 7, 8, 9 and/or 10 of SEQ ID NO:3 to the formation of a duplex in the normal control sample between said oligonucleotide and said target region in exon 2, 3, 4, 5, 6, 7, 8, 9 and/or 10 of SEQ ID NO:3 ~~between the target region and the oligonucleotide~~; wherein the presence of the duplex in the nucleic acid sample is indicative of the wildtype target region and the absence of the duplex is indicative of a mutation in the wildtype target region ~~a change in the formation of the duplex in comparison to~~

~~formation of a control duplex comprising the oligonucleotide and the wildtype target region of SEQ ID NO:2 is indicative of the presence of the mutation~~.

45. (currently amended) A method for detecting the presence or absence of a mutation in a target region in exon 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3 in a nucleic acid sample, the method comprising:

amplifying the target region in exon 2, 3, 4, 5, 6, 7, 8, 9 and/or 10 of SEQ ID NO:3 in the nucleic acid sample and the target region in exon 2, 3, 4, 5, 6, 7, 8, 9 and/or 10 of SEQ ID NO:3 in a normal control sample comprising the wildtype exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3 with primer pairs specifically amplifying exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3, either individually or in groups;

contacting amplified product from the nucleic acid sample with an oligonucleotide corresponding to the wildtype SEQ ID NO:3, wherein the oligonucleotide discriminates between the wildtype gene and mutant form in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3;

contacting amplified product from the normal control sample with said oligonucleotide; and

comparing the formation of a duplex in the nucleic acid sample between said oligonucleotide and said target region in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of

SEQ ID NO:3 to the formation of a duplex in the normal control sample between said oligonucleotide and said target region in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3; wherein the presence of the duplex is indicative of the wildtype target region and the absence of the duplex is indicative of a mutation in the wildtype target region.

~~incubating the nucleic acid sample in an amplification reaction comprising primers that amplify the target region in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3;~~

~~contacting the amplified product with an oligonucleotide probe to the amplified target region of SEQ ID NO:3; and,~~

~~detecting the formation of a duplex between the amplified product and the oligonucleotide probe; wherein a change in the formation of the duplex in comparison to formation of a control duplex comprising the oligonucleotide and the wildtype target region of SEQ ID NO:3 is indicative of the presence of the mutation.~~

47. (currently amended) A method for detecting the presence ~~or absence~~ of a mutation in a target region in exon 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3 in a nucleic acid sample, the method comprising:

incubating the nucleic acid sample ~~from the individual~~ in an amplification reaction comprising primer pairs for specifically amplifying exons 2 through 10 of MEN1, SEQ ID NO:3 either individually or in groups ~~primers that amplify a target region of SEQ ID NO:3~~; and

determining the sequence of the target region, wherein a change in sequence in comparison to SEQ ID NO:3 is indicative of the presence of a mutation.

4. Authorization for this Examiner's Amendment was given in a telephone interview with Jean Lockyer on October 25, 2007.

5. The following is an Examiner's Statement of Reasons for Allowance:

In view of the amendment of the claims, the previously cited rejections are hereby withdrawn. The claim amendments are fully supported by the careful and complete teaching of the specification, wherein the specification clearly teaches not only the method claimed but also the oligonucleotides and primers that discriminate between the wildtype gene and mutant form in exons 2, 3, 4, 5, 6, 7, 8, 9, and/or 10 of SEQ ID NO:3 at Table 1, wherein support for newly added claim language can be found throughout the specification.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should

preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
October 29, 2007